REMARKS

Reconsideration And Allowance Are Respectfully Requested.

Claims 1-15 are currently pending. Claims 1-3 have been amended to replace the terms "monochromatic, coherent" with "laser". No claims have been canceled. No new matter has been added. The amendment to claims 1-3 in no way can be considered a material change, since the Examiner has indicated in the Office Action that "monochromatic, coherent" is inherently laser light. Reconsideration is respectfully requested.

Claims 1-15 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,676,655 to McDaniel (McDaniel). McDaniel discloses a method for treating skin disorders with electromagnetic radiation generated by an Nd:YAG laser in the wavelength range of 1,064 nm, but fails to teach Applicant's dosage.

Specifically, Applicant claims treating for a sufficient treatment time to produce clinically beneficial effects by delivering a dosage greater than 20 joules/cm^2 . This is more than twice that disclosed by McDaniel. In fact, McDaniel is generally only concerned with a dosage of up to 1 J/cm^2. McDaniel's treatment dose, or energy fluence, at best is only up to 10 J/cm^2.

There is, however, one occurrence of the language "around 0.01 – 100.0 Joules/cm^2" within the specification of McDaniel. However, it is clear when this statement is considered in conjunction with the remainder of the specification, previously filed parent applications, and an understanding of the technology, the statement of McDaniel of "around 0.01 – 100.0 Joules/cm^2" is a typographical error.

Although this language is included in the specification of McDaniel, it is not supported by the remaining disclosure in McDaniel.

First, the parent applications from which the 6,676,655 patent to McDaniel's depends include the following language: "around 1.0-10.0 Joules/cm^{2}" (See attached Exhibit A which includes highlighted printouts of columns 7 and 8 of the 6,283,956 and 6,629,971 patents). As such, it appears that a typographical error must have occurred when adding language to the paragraph and extra zeros were added.

Second, throughout the remainder of the specification, McDaniel specifically limits the energy fluence received by said tissue to less than about 10 J/cm^2. This provides further evidence the one statement of "around 0.01 – 100.0 Joules/cm^{2}" was improper as it does not correspond with the rest of the specification and is not supported by the remainder of the specification.

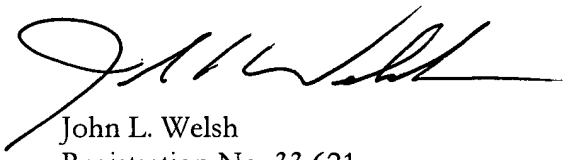
Third, the only other time 100.0 occurs is when McDaniel discloses the use of 100.0 milliJ/cm^2 in Examples 3 & 4, not 100.0 Joules/cm^2.

Fourth, prior to Applicant no one of skill in the art even contemplated 100.0 Joules/cm^2 and neither did McDaniel. That is why it is not discussed, but merely erroneously typed.

Therefore, McDaniel fails to meet all of the claimed limitations and does not anticipate or render obvious Applicant's claimed invention. That is, up to 10 J/cm^2 is not the same as 20 J/cm^2 or more as claimed by Applicant.

For the foregoing reasons, the 35 U.S.C. § 102 rejection based upon McDaniel is deemed to be improper and should be withdrawn. All of the pending claims are now believed to be in condition for allowance and Applicant respectfully requests that a Notice of Allowance be issued. If additional information is required, or if the Office has any questions that might expedite prosecution of the above-referenced application, the Office is urged to contact the undersigned at (703) 920-1122.

Respectfully submitted,



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of delivered energy than that used for hair reduction. Phonophoresis may be used to deliver other stimulating or growth supporting agents.

In one embodiment a process in accordance with the present invention may be used to provide short or long-term control, improvement, reduction or elimination of acne or other skin diseases. An active agent may be physically or chemically or immunologically incorporated into cells of the sebaceous (oil) glands or into the naturally occurring acne bacteria, yeast or similar organisms which feed on the oil in the oil glands (or sweat glands)or are otherwise relatively benign inhabitants. Improvement in skin disorders may be a direct or indirect result of the application of the agents in this process, as may reduced oiliness of the skin, reduced size or diminished appearance of pores, etc.

Other similar disorders such as folliculitis which involve the pilo-sebaceous (hair/oil gland) unit may also be treated using the present invention. The present invention may also be used to reduce perspiration, sweating, or hyperhidrosis from eccrine (sweat) glands or apocrine glands. A preferred embodiment of the present invention may be used to treat other skin disorders such as, for example, viral warts, psoriasis, precancerous solar keratosis or skin lesions, hyperhidrosis/excessive sweating, and perhaps skin ulcers (diabetic, pressure, venous stasis).

A preferred embodiment of the present invention may use various microencapsulation processes to deliver active agents. If the diameter of the micro encapsulations is about five microns, then there may be relatively site specific preferential delivery into the sebaceous oil glands or skin surface stratum corneum cells. If the diameter of the microencapsulations is in the range of about one micron, then the active agents may be delivered with a more random distribution between the hair ducts and the oil glands. If the diameter of the microencapsulations is larger, on the order of about 20 microns or greater, then delivery will tend to be restricted primarily to the skin surface. The micro encapsulations may be synthetic or natural. If ultrasound is used to enhance penetration, then the diameters and ultrasound treatment parameters may need to be adjusted according to the applicable principles which allo the estimation of the optimal ultrasound parameters for driving small particles into the skin, skin appendages or skin orifices.

Microencapsulation may be used to improve delivery of known agents such as indocyanine green and particles of carbon or graphite. A known technique for using a laser to produce a wavelength that may be absorbed by indocyanine green for a hair removal treatment process is described, for example, in U.S. Pat. No. 5,669,916, which is incorporated by reference. It has been found that by using smaller particles and putting the smaller particles into more uniform diameter microencapsulations, more site specific or uniform targeting may be achieved. A preferred formulation may include indocyanine green or other dyes or agents to form a lipid complex which is fat-loving (lipophilic). The delivery and clinical effects of agents and dyes such as indocyanine green dye may be refined and enhanced by selecting a carrier or encapsulation having a diameter that increases the probability of preferential delivery to a desired space, and/or that enables interaction with ultrasound to thereby increase the probability of preferential delivery, and/or that selectively attaches to the sebaceous gland and/or hair.

Indocyanine green dye is presently in medical use, appears to be relatively benign, may be activated by red visible lasers (in the 800 nm range) may penetrate deeply enough to reach the oil glands, is used for leg vein and hair removal, and is relatively safe, cheap, and reliable. A known technique for using a laser to produce a wavelength that may be absorbed by indocyanine green for use in a leg vein treatment process is described, for example, in U.S. Pat. No. 5,658,323, which is incorporated by reference.

The microsponges containing the active agent may selectively attach, or at least have a chemical affinity for, some part of the oil gland. The ICN dye may be conjugated with lipids, which would then have an affinity for the oil glands. Alternatively, the attachment may occur after the active agent is released from the microsponge, either passively or by attractive or chemical forces. In the case of some microencapsulation carrier vehicles, release may occur after disruption of the vehicle integrity itself, possibly by ultrasound or laser or light or other energy source or perhaps a chemical reaction.

In a preferred embodiment the ICN dye may be mixed with lipids, or put into microsponges (a.k.a. microspheres), and then applied to the skin surface, allowed to sit for a time. Excess dye may be removed, and then the area may be treated with laser light at about 800 nm, between about 0.1 and 100 millisec pulses and around 1.0–10.0 Joules/cm^2.

U.S. Pat. No. 5,817,089 specifies "particles having a major diameter of about 1 micron". It has been discovered, however, that these diameters may not be optimal. A 1993 Pharmaceutical Research journal article by Rolland et al describes an acne treatment wherein a topical acne drug is delivered with less irritation by putting the drug into synthetic polymer microsphere sponges. This article reported that an optimal diameter for site-specific delivery into sebaceous oil glands in the skin was about 5 microns, and that 1 micron particles randomly delivered to the hair follicle and stratum corneum.

Most agents may not inherently be the optimal size. However, virtually any agent may be preferentially delivered to the sebaceous glands by either synthetic microspheres, or liposomes, or albumen microspheres, or other similar "delivery devices".

In a preferred embodiment for treatment of acne, graphite particles having an average diameter of about one micron may be placed in delivery devices, such as microsponges, having an average diameter of about five microns. The microsponges may then be suspended in a lotion. Ultrasound may be used to drive the particles into the skin. The optimal ultrasound parameters may be based on the outside particle diameter (especially if particles are uniform). Selective delivery of the particles to hair and perhaps to sweat glands may be improved.

Use of such applications could enable selective delivery of anti-acne agents, or hair dye for laser hair removal, or agents which stimulate hair growth, or other hair treatments, where the encapsulation diameter was used, with or without ultrasound, to preferentially deliver, and ultrasound at different parameters or laser was used to release (not necessarily to activate or interact).

These techniques may be applied to many other agents in addition to ICN dye and graphite lotions. The term "encapsulated delivery device" is used herein as a generic term which encompasses all such possible items.

Pressure may be used to impel particles (i.e., graphite, carbon, or other active agent or skin contaminant particulates) into the skin, either in the spaces between the stratum corneum, into the hair ducts and hair follicles, the sebaceous oil glands, or other structures. Air pressure or other gases or liquids may be used to enhance delivery-or increase the quantity of delivered agent. A known technique

control, improvement, reduction or elimination of acne or other skin diseases. An active agent may be physically or chemically or immunologically incorporated into cells of the sebaceous (oil) glands or into the naturally occurring acne bacteria, yeast or similar organisms which feed on the oil in the oil glands (or sweat glands)or are otherwise relatively benign inhabitants. Improvement in skin disorders may be a direct or indirect result of the application of the agents in this process, as may reduced oiliness of the skin, reduced size or diminished appearance of pores, etc.

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Ultrasound may be used to physically deliver hair dye and to enhance penetration into the hair shaft itself (see, for example, U.S. Pat. No. 5,817,089, incorporated herein by reference). The use of ultrasound to physically drive graph-